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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,518	08/01/2005	Patrick D Kane	0289713.00123US3	8868
23483	7590	02/23/2009	EXAMINER	
WILMERHALE/BOSTON			KISHORE, GOLLAMUDI S	
60 STATE STREET			ART UNIT	
BOSTON, MA 02109			PAPER NUMBER	
			1612	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/510,518	Applicant(s) KANE, PATRICK D	
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10-7-04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims included in the prosecution are 1-16.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3, 10-13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The examiner suggests the deletion of 'including' in claim 3. 'any' is an indefinite term. Specific methods should be recited.

'any composition renders claim 10 indefinite; specific compositions should be recited.

It is unclear as to what 'polysorbate 80/85 is intended to convey in claim 11.

It should be 'said condition in claim 9' in claim 13.

What is being conveyed in claim 16? What are the conditions to be treated?, 'What is being conveyed by 'influenced'? influenced by what? 'The examiner suggests the deletion of 'including' and amend the claim to recite clearly the conditions to be treated.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Schneider (6,258,378) of record.

Schneider discloses a method of delivery of biologically active substances encapsulated in liposomes or microparticles and applying ultrasound. Antibodies are attached to the surface of the liposomes to selective targeting (col. 2, line 62 through col. 6, line 67, Examples and claims).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitragotri (5,814,599).

Mitragotri discloses transdermal delivery of active agents encapsulated in liposomes or microparticles and applying ultrasound (col. 4, line 55 through col. 6, line 11, examples and claims).

6. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Morrison (6,099,864).

Morrison discloses a method of delivery of biologically active substances encapsulated in liposomes or microcapsules and applying various forms of energy such as light, microwave and ultrasound (col. 5, line 60 through col. 11, line 6, Examples and claims).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider or Morrison cited above in view of Micklus (200/0025313) or vice versa.

Schneider as discussed above discloses a method of delivery of biologically active substances encapsulated in liposomes or microparticles and applying ultrasound. Antibodies are attached to the surface of the liposomes to selective targeting (col. 2, line 62 through col. 6, line 67, Examples and claims). Schneider however, does not teach that the antibodies to be anti-transferrin antibodies to carry the liposomes across the blood-brain barrier.

Morrison as discussed above discloses a method of delivery of biologically active substances encapsulated in liposomes or microcapsules and applying various forms of energy such as light, microwave and ultrasound (col. 5, line 60 through col. 11, line 6, Examples and claims). Morrison however, does not teach that the antibodies to be anti-transferrin antibodies to carry the liposomes across the blood-brain barrier.

Micklus teaches that drugs can be transported across the blood-barrier using liposomes attached to anti-transferrin antibodies. The therapeutic agents include those used for the treatment of Parkinson's disease, conditions associated with pain, disorders of movement, cognition and behavior and chemotherapeutic agents (0009-0036, Examples and claims). What is lacking in Micklus is the use of ultrasound to release the active agent from the liposomes.

It would have been obvious to one of ordinary skill in the art to use anti

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transferrin antibodies as the specific antibodies taught by Schneider or attach antibodies to the liposomes of Morrison since such a use would enable the liposomes cross the blood-brain barrier if the conditions to be treated are such as Parkinson's disease, pain management and others as taught by Micklus. Alternately, to use ultrasound to the liposomes of Micklus would have been obvious to one of ordinary skill in the art since Schneider teaches that the active agents are released by such treatment. Although Schneider, Morrison, and Micklus do not teach viral vectors (nucleic acids) or gene therapy since they teach therapeutic agents in general and since nucleic acids are well-known in the art as therapeutic agents, it would have been obvious to one of ordinary skill in the art to use these therapeutic agents with a reasonable expectation of success.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mitragotri (5,814,599).

Mitragotri as discussed above discloses transdermal delivery of active agents encapsulated in liposomes or microparticles and applying ultrasound. The therapeutic agents include nucleic acids (col. 4, line 55 through col. 6, line 11, examples and claims). Mitragotri however, does not specifically teach that the nucleic acids are viral in origin. In the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to use viral nucleic acids in Mitragotri with a reasonable expectation of success.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is

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(571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK